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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,582	07/13/2001	Song Hu	CL001274	6381

25748 7590 11/22/2006

CELERA GENOMICS
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EXAMINER	
CROWDER, CHUN	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,582	HU ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/26/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 24-38* is/are pending in the application.

4a) Of the above claim(s) *1,2,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures..

DETAILED ACTION

1. The examiner of this application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Chun Crowder, Group Art Unit 1644, Technology Center 1600.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Short amino acid sequences are disclosed on page 1 of Figure 2. However, the sequences fail to comply with the Sequence Rules.

Applicant is reminded of the Sequence Rules which require a submission for all sequences of 10 or more nucleotides or 4 or more amino acids (see 37 CFR 1.1821-1.1825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

Applicant must comply with the requirements of the Sequence Rules (37 CFR 1.1821-1.1825) in response to this Office Action.

3. Applicant's election with traverse of Group II encompasses an isolated antibody, filed 08/26/2005, is acknowledged.

The traverse is on the ground that search and examination of Group I, drawn to a polypeptide and Group II, drawn to an antibody, together would not constitute an undue burden for the Examiner because both groups are based on the amino acid sequence of the polypeptides.

This is not found persuasive for reasons of record set forth in the previous Office Action, mailed 07/29/2005. Further, Groups I and II are distinct because polypeptide and its antibody have a materially different design, mode of operation, function, or effect; they do not overlap in scope, i.e., are mutually exclusive; and the inventions as claimed are not obvious variants. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Therefore, it is undue burden on the Examiner to search more than one invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-23 have been canceled.
Claims 24-38 have been added.

Claims 1-3 and 24-38 are pending.

Claims 1, 2, 37, and 38 have been withdrawn from further consideration by the Examiner, under 37 C.F.R. 1.142(b), as being drawn to nonelected invention.

Claims 3 and 24-36 are currently under consideration.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

5. Applicant's IDSs, filed 10/23/2003 and 08/26/2005, are acknowledged and have been considered.

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, e.g. on page 10 of the instant specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP §608.01.

In addition, the application is required to be reviewed and all spelling, TRADEMARK, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent application, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 3 and 24-36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility.

The claimed antibody that selectively binds to a polypeptide with amino acid sequence set forth in SEQ ID NO:2 are not supported by a specific asserted utility because the disclosed uses of the antibody are not specific and are generally applicable to any antibody.

The instant specification discloses that the polypeptide with amino acid sequence of SEQ ID NO:2 has been identified as being member of the secreted protein family and are related to the serine protease inhibitor protein subfamily (see pages 6 of the specification); the protein is expressed in testis and brain and can be used to raise antibodies, serve as targets for identifying agents for use in therapeutic applications (see pages 14-21 of the instant specification). The specification on pages 23-25 further discloses that the antibody selectively binds to polypeptide of SEQ ID NO:2 can be used to isolate and detect the protein. These are non-specific uses that are applicable to antibodies in general and not particular or specific to the antibody being claimed.

Further, assignment to a prior art family of proteins is insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific and substantial use to the new member of the protein family. Since the specification fails to teach a specific function of the recited sequence, sequence homology alone is insufficient to provide a use for claimed polypeptide of SEQ ID NO:2. The serine protease inhibitor family (Serpin) (Sheng. Journal of Cellular Physiology. 2006. 209:631-635. See Abstract on page 631, in particular) represents a superfamily of homologous proteins with diverse range of functions including blood coagulation, fibrinolysis, programmed cell death, development and inflammation (Glyn et al. Frontiers in Bioscience 2005. 10:288-299. See Introduction on pages 288-289, in particular). Therefore, the activity and function of the claimed polypeptide with amino acid sequence of SEQ ID NO:2 based solely on sequence similarity with serine protease inhibitor family does not constitute a specific and substantial utility; thus the claimed antibody that selectively binds to SEQ ID NO:2 does not have a specific utility.

Furthermore, the claimed antibody is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a polypeptide can be used to make antibody. The antibody can then be used in conducting research to isolate, purify or detect the protein which itself has no known utility. The need for such research clearly indicates that the biological functions of the protein and the antibody are not disclosed as a currently available or substantial utility. A stating material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case, the protein that are isolated or purified by the claimed antibody has no asserted or identified specific and substantial utilities. The research contemplated by applicant to detect and assess the expression and distribution of the protein does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself (e.g. expression and distribution) do not define a "real world" context or use.

Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set for the above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the antibody such that another non-asserted utility would be well established for the antibody.

Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 3 and 24-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 3 and 24-36 are rejected under 35 U.S.C. 102(a) as being anticipated by Fernandez et al. (WO 00/61754. Reference cited in IDS filed 10/23/2003) (see entire document) as evidenced by as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886).

Fernandez et al. teach an isolated polynucleotide encoding a protein with 842 amino acid residues set forth in SEQ ID NO:16 and its fragments, analogs, homologs and derivatives (see entire document, particularly page 13 of the specification); the N-terminal of the referenced protein from amino acids 1-243 is 98.3% identical to the claimed SEQ ID NO:2. Further, Fernandez et al. teach that the protein with amino acid sequence of SEQ ID NO:16 and its variants can be used to make antibodies, such as monoclonal antibodies and antibody fragments including an Fab fragment, $F(ab')_2$ fragment and single chain Fv fragment (see pages 36-37, in particular); and the antibodies can be coupled to a detectable substance such as various enzymes and fluorescent materials (see page 39, in particular). Moreover, Fernandez et al. teach that the antibodies can be formulated in pharmaceutical composition comprising pharmaceutically acceptable carriers (e.g. see page 45-46, in particular).

As evidenced by Bost et al, antibodies can be specific and cross-react with the antigen. For example, antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (e.g., "Results, page 579).

As further evidenced by Bendayan, the specific reactivity of a monoclonal antibody can be highly specific yet cross-react with antigens from different species or even distinct proteins not related to the original antigen (page 886, last paragraph).

Consequently, it was well known in the art at the time the invention was made that antibody binding of distinct proteins was indeed specific. Therefore, the reference antibody to SEQ ID NO:16 is specific to the claimed SEQ ID NO:2.

Therefore, the reference teachings anticipate the claimed invention.

13. Claims 3 and 24-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et a. (WO 01/57190) (see entire document) as evidenced by as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886).

Tang et al. teach and an isolated protein with 838 amino acid residues set forth in SEQ ID NO:3151 and its fragments, analogs, homologs and derivatives (see entire document, particularly pages 28 and 267 of the specification); the N-terminal of the referenced protein from amino acids 1-243 is 96.5% identical to the claimed SEQ ID NO:2. Further, Tang et al. teach that the protein and its variants can be used as immunogens to make antibodies, such as monoclonal antibodies and antibody fragments including an Fab fragment, $F(ab')_2$ fragment and single chain Fv fragment (see pages 74-81, in particular); and the antibodies can be coupled to a detectable substance such as ^{131}I, (see page 84) and enzymes (see page 89, in particular). Moreover, Tang et al. teach that the antibodies can be formulated in pharmaceutical composition comprising pharmaceutically acceptable carriers for method of treatment (see claim 28 on page 483, in particular).

As evidenced by Bost et al, antibodies can be specific and cross-react with the antigen. For example, antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (e.g., "Results, page 579).

As further evidenced by Bendayan, the specific reactivity of a monoclonal antibody can be highly specific yet cross-react with antigens from different species or even distinct proteins not related to the original antigen (page 886, last paragraph).

Consequently, it was well known in the art at the time the invention was made that antibody binding of distinct proteins was indeed specific. Therefore, the reference antibody to SEQ ID NO:3151 is specific to the claimed SEQ ID NO:2.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
November 1, 2006

PHILLIP GAMBEL, PH.D JD
PRIMARY EXAMINER
TC 1600
11/6/06

Notice to Comply	Application No. 09/903,582	Applicant(s)	
	Examiner Chun Crowder	Art Unit 1644	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e). The correct SEQ ID NO:2 is present in the paper copy of the of the sequence listing only. Therefore a search of the correct sequence is not possible.

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.**

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
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